

## REMARKS

The foregoing Amendment and remarks which follow are further to Applicants' amendment dated June 14, 2000, in relation to the above-identified patent application. Such previously-filed amendment was in response to the non-final Office Action mailed December 15, 1999 wherein Claims 181-188 were rejected 35 U.S.C. §102(b) as being anticipated by MORRISON (i.e., United States patent No. 5,584,818).

In this regard, the previously-submitted amendment, which sought to amend the claims to distinguish the present invention over the prior art, namely, the MORRISON reference, did not necessarily reflect the intent of the Applicants, nor was consistent with the claim numbering that has evolved in this case. Accordingly, to clarify such matters, Applicants respectfully request that the present amendment supercede such earlier-filed amendment, and that the same serve to dispel any doubt as to Applicants' intent.

With respect to the new claims 189-200 presented herein, Applicants respectfully submit that the same more clearly and precisely define the subject matter of the present invention and further, are readily distinguishable from the MORRISON reference. In this respect, Applicants respectfully submit that the MORRISON reference neither teaches nor discloses a needle protective device comprising, inter alia, a needle guard slidably mounted upon a needle, whereby the needle has a proximal end and a sharp distal end with at least one change of profile formed thereon, and the needle guard has a movable needle trap, the latter having a limiting apparatus engageable with said at least one change in profile for limiting the distance the needle trap travels upon the needle.

More specifically, the safety hypodermic needle and shielding cap assembly disclosed in MORRISON comprises the combination of a safety shield and a leaf spring. According to such reference, the safety shield is movable about the length of the cannula, and is biased toward the distal end thereof by the leaf spring. Once the safety shield has been extended to the distal-most end of the cannula, a cover plate formed on the cover spring covers the distal-most end of the

needle tip with the leaf spring preventing further distal movement of the safety shield, thus causing the same to remain in relatively fixed position relative the distal end of the needle.

The present invention, in contrast, does not necessarily incorporate a leaf-spring.<sup>1</sup> The newly-presented claims likewise omit any type of biasing member for urging the needle guard toward the sharpened distal end of the needle.

Rather, the instantly claimed invention comprises devices depicted in Figures 6-7 and 106-108, and discussed in the specification at Page 83, line 18 to Page 87, line 16. Support for such devices, may further be found in Figures 97-102 and more particularly the change in profile formed upon the needle and discussed in the specification at page 74, line 15 to page 79, line 6. In this respect, the needle protective devices of the present invention utilize a change in profile formed upon the needle which forms a unique mechanism by which the distance the needle guard travels upon the needle is limited, particularly when the needle trap assumes the operative configuration to trap the sharpened distal end of such needle. As specifically depicted in such Figures, and as stated in the specification, such change in profile may comprise either a recessed change in profile (See, e.g., Figure 106, page 83, lines 20-21), an oversized, outwardly-extending sidewall portion (See, e.g., Figure 108, page 84, lines 18-19), or a combination of opposed recessed portions and outwardly-extending sidewall portions formed relative the needle (See, e.g., Figure 107, page 85, lines 12-14). With respect to the latter, it should be noted that Figures 106 and 107 depict a side cross sectional view and a top-cross sectional side view, respectively, of the same needle guard of the present invention and reflect a change of profile comprised of both recessed and outwardly-extending sidewall portions utilized to limit axially movement of the slidable needle guard relative the needle tip.

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To dispel any ambiguity with regard to Applicants' previously-filed amendment, which reflected that the needle guard devices of the present invention must necessarily include a "biasing apparatus", Applicants wish to advise the Examiner that such element, although not presently claimed and not an essential component of the embodiments sought to be patented, could be incorporated as part of the needle protective devices of the present invention.

Consistent with the authority cited in Applicants' earlier amendment, anticipation cannot be established unless a single prior art reference discloses each and every element of the claimed invention. Structural Rubber Co. vs. Park Rubber Co., 749 F.2d 707, 223 USPQ 1264 (Fed.Cir. 1994). Moreover, for anticipation to apply, all of the claimed elements must be found in exactly the same situation and united in the same way to perform the identical function in a single unit of the prior art. See, e.g., Studiengesellschaft Kohle M.B.H. vs. Dart Industries, 762 F.2d 724, 726, 220 USPQ 841, 842 (Fed.Cir. 1984). Accordingly, by virtue of the fact that Applicants' apparatus for introducing an intravenous catheter neither includes a leaf spring, nor any other apparatus for that matter for biasing the needle trap forward, Applicants respectfully submit that rejection of the newly-amended claims under §102 cannot be maintained.

In light of the foregoing amendment and remarks, Applicants respectfully submit that all of the claims are allowable and are in a condition for immediate allowance. Early notice to that effect is respectfully requested.

To the extent the Examiner has any questions, requires additional information, or has any suggestions to expedite resolution of any outstanding matters, he is invited to contact Applicants' counsel at the number listed below.

Respectfully submitted,

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